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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,532	10/15/2003	Karl Guegler	CL000861CON	5244
25748	7590	03/03/2006	EXAMINER	
CELERA GENOMICS ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY 45 WEST GUDE DRIVE C2-4#20 ROCKVILLE, MD 20850			ULM, JOHN D	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/684,532	Applicant(s) GUEGLER ET AL.	
	Examiner John D. Ulm	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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- 1) Claims 17 to 30 are pending in the instant application.
- 2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4) Applicant has been advised that the listing of references in the specification is not a proper information disclosure statement. Applicant has responded by asserting that "Applicants do not believe there is a listing of references in the specification and request that the Examiner identify where this listing of references is located". Applicant is advised that references are cited throughout the body of the specification and Applicant's attention is directed, for example, to the paragraph bridging pages 6 and 7 therein.
- 5) Claims 17 to 30 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 4 of the previous office action. As stated therein, the instant claims are drawn to an antibody that "specifically" binds to a polypeptide consisting of the amino acid sequence presented in SEQ ID NO;2 of the instant application. The4 claimed antibodies lack a specific and substantial utility because the instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder of physiological process which one would wish to diagnose, measure or manipulate for a desired clinical effect.

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Applicant has traversed this rejection on the premise that “the specification on page 5” states that “this protein belongs to the SLC26 family and has been identified as being a transporter of chloride, oxalate and sulfate”. Applicant has mischaracterized the statement on page 5 of the specification, which teaches that “[t]he novel human protein, and encoding gene, provided by the present invention **is related to** anion transporters in general, and the SLC26 anion transporter subfamily in particular” and that “[a]nion transporters, such as members of the SLC26 family, transport anions such as chloride, iodine, bicarbonate, oxalate, and hydroxy across plasma membranes”. Nothing in the text on page 5 of the instant specification expressly states that a protein comprising the amino acid sequence presented in SEQ IN NO:2 of the instant specification transports chloride, oxalate and/or sulfate across a cell membrane. Further, the assertion that a protein of the instant invention is an anion transporter does not constitute an assertion of a utility, only a discloser of an inherent property of that protein.

Applicant further asserts that “diseases associated with anion transporters have been identified”. The instant specification has failed to identify any particular disease or disorder that **has been shown** to be associated with a protein of the instant invention. Those arguments that are based upon the discoveries identified in the Lohi et al. publication are irrelevant to the instant rejection because Applicant can not rely upon discoveries by themselves or others that are made after the filing of the instant application to complete the claimed invention. It is a matter of law that an invention must have a specific and substantial utility “in currently available form”, which precludes the

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need for further research, if that research is needed to establish a utility for the claimed invention (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)),. When additional experimentation is required to identify or reasonably confirm a specific and substantial utility for a claim product then that product lacked utility at the time that the application was filed. In the decision *In re Lundberg*, 117 USPQ 190, 1958, the CCPA held that "advantages which are not disclosed in application cannot be urged as basis for allowing claims".

6) Claims 17 to 30 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Claims 18, 20, 22, 24, 26, 28 and 30 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record in section 6 of the previous office action. As stated therein, because of the presence of the term "comprises SEQ ID NO:2", these claims encompass an antibody which binds to an epitope that is not contained within SEQ ID NO:2. Applicant is advised that the limitation "selectively binds" requires an antibody to bind to a protein containing its respective epitope without binding to a protein lacking that epitope. Nothing in the limitations of the instant claims requires the recited antibody to bind to an epitope contained within SEQ ID NO:2. Therefore, they encompass any antibody which can bind to any epitope which can be expressed as a portion of a polypeptide

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comprising the amino acid sequence as set fourth in SEQ ID NO:2 and, therefore they essentially encompass any antibody which can bind to any polypeptide or protein. The instant specification, however, does not provide a written description or the guidance needed to produce an antibody which binds to any epitope other than an epitope which is contained within SEQ ID NO:2 of the instant application. Applicant's traversal of this rejection is not persuasive because it completely ignores the basis upon which the rejection was made.

8) Claims 18, 20, 22, 24, 26, 28 and 30 stand rejected under 35 U.S.C. 102(b) as being anticipated by the Hopp et al. patent (5,011,912) for those reasons of record in section 7 of the previous office action. As explained above, these claims encompass an antibody which binds to any antigenic peptide, including the flag epitope DYKDDDDK which was bound by the antibody of Hopp et al. prior to the time of the instant invention.

9) Applicant's arguments filed 19 December of 2005 have been fully considered but they are not persuasive.

10) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

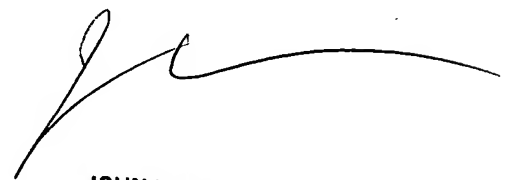
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM
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